

DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gary Gershik on April 19, 2011.

Claims are amended as follows:

In claim 30, line 3, insert --in need thereof-- after "a patient".

In claim 30, lines 4-6, delete [10mg of oxandrolone per day, up to 100mg oxandrolone per day] and replace with --10 mg to 100 mg of oxandrolone per day in conjunction with a protein supplement to achieve a daily protein intake by the patient of approximate 2.0 g/kg/day--.

In claim 30, lines 7-10, delete [so as to promote weight gain in said patient wherein the weight gained is maintained at eight weeks after discontinuation of the oxandrolone administration].

In claim 44, delete [the weight gained comprises lean body mass] and replace with – the weight gain comprises lean body weight gain-- in line 2.

Cancel claims 43 and 47.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The prior art of record does not fairly teach, suggest, or disclose to treat a patient with weight loss resulting from post-burn catabolism for promoting weight gain by administering oxandrolone in conjunction with a protein supplement in a specific regimen as claimed. The prior art of record provides no direction regarding treating the particular subset of patients (i.e. patients in need of promoting weight gain after weight loss resulting from post-burn catabolism) as claimed, nor the unexpected results Applicant has observed therewith (e.g. the administration of oxandrolone in conjunction with a protein supplement provides nearly double the amount of weight gain as compared to the amount of weight gain with protein supplementation alone and nearly four times the amount of weight gain as compared to a group of ideally nutritionally managed burn patients and the weight gained remains at eight weeks after discontinuation of the oxandrolone administration). Also see applicant's argument filed on 9/8/2009.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 30, 32-34, 36-42, and 44 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 9:00 am-6:00 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BONG-SOOK BAEK
Examiner, Art Unit 1629

Bbs

/Jeffrey S. Lundgren/
Supervisory Patent Examiner, Art Unit 1629